ORIGINAL

TSCA NON-CONFIDENTIAL BUSINESS INFORMATION DOCUMENT CONTROL NUMBER **DATE RECEIVED DOCUMENT DESCRIPTION** 88110000330 8EHQ-11-18446 9/20/11 COMMENTS:

DOES NOT CONTAIN CBI

Akzo Nobel Services Inc.

525 West Van Buren Street T +1 312 544 7000 Chicago, IL 60607-3835 United States

F+1 312 544 7125 RECEIVED



2011 SEP 20 AM 10: 49



September 19, 2011

Office of Pollution Prevention and Toxics EPA East – Room 6428 Attn: Section 8(e) U.S. Environmental Protection Agency 1201 Constitution Avenue, NW Washington, DC 20004-3302



ATTENTION: TSCA 8(e) Notice

Dear U.S. EPA:

On behalf of Akzo Nobel Surface Chemistry LLC, we are submitting results from an OECD 407, 4-week repeated dose study including a 4-week recovery period on Coco amidopropyldimethylamine (CAS# 68140-01-2) under Section 8(e) of TSCA.

In the OECD 407 study, groups of 5 male and 5 female rats were treated by gavage once daily for up to 29 consecutive days. In this study two satellite groups of 5 male and 5 female rats were included in the control group and the high-dose group. These animals were kept for a 4-week recovery period after treatment for observation of reversibility, persistence or delayed occurrence of systemic / irritative effects. The Control Group was dosed with the vehicle only (corn oil).

The following dose levels were selected as follows:

- Control Group: 0 mg/kg body weight/day
- Low Dose Group: 30 mg/kg body weight/day
- Mid Dose Group: 60 mg/kg body weight/day
- High Dose Group: 120 mg/kg body weight/day

A trend towards a lower body weight gain was noted in treated animals associated with a decrease in food consumption in high-dose group when compared to control group. These effects were reversible during the recovery period.

At necropsy white discoloration of the fore stomach was observed in the mid- and highdose groups confirming the strong irritative/corrosive properties of the test substance. In the satellite groups no test item-related changes were observed at necropsy. Microscopic examination revealed signs of pronounced irritation of the fore stomach in





Page 2 of 2 September 19, 2011

the mid- and high-dose groups. These signs consisted of acanthosis, hyperkeratosis, erosion/ulcer, edema with mixed infiltrate of inflammatory cell in the submucosa and correlated with the white discoloration seen at necropsy. In the low-dose group changes in the fore stomach were also present but with lower severity and incidence.

Furthermore, the microscopic examination after a 4-week recovery period showed a pronounced decrease in the incidence and severity of changes observed in the fore stomach but the recovery was not complete. Acanthosis and hyperkeratosis were still observed.

The NOAEL with respect to systemic toxic effects was considered to be 60 mg/kg/day because of lower food intake and slight reduction in body weight gain observed in animals treated at 120 mg/kg/day. A NOAEL for local effects could not be established because of irritation observed in the fore stomach of all treated groups. However, in the absence of a similar structure in the human stomach, the relevance of the findings in the rat non-glandular portion of the stomach (fore stomach) with respect to human health is not known.

Please contact me if you have any questions at 312-544-7191.

Sincerely,

Edwin C. Bisinger Jr., PhD, DABT

EcBinger

Director, Global Product Safety

HSE Department

Akzo Nobel Services Inc.

525 W. Van Buren St.

Chicago, IL 60607-3835

From: (312) 544-7089 Jennifer Wisniewski

525 W Van Buren St Suite 1600 Chicago, IL 60607

Origin ID: GYYA



Ship Date: 19SEP11 ActWgt: 0.5 LB CAD: 103210438/INET3180

SHIP TO: (202) 564-8940 BILL SENDER

Office of Pollution Prevent & Toxic **U.S. Environmental Protection Agncy** 1201 CONSTITUTION AVE NW ATTN:SECTION 8(E); EPA EAST-RM 6428 **WASHINGTON, DC 20460**



Invoice # PO # Dept #

TRK# 7952 0184 4241

TUE - 20 SEP A1 STANDARD OVERNIGHT

XC RDVA

20460 DC-US **DCA**



- After printing this label

 1 Use the 'Print' button on this page to print your label to your laser or inkjet printer

 2 Fold the printed page along the horizontal line

 3 Place label in shipping pouch and affix it to your shipment so that the barcode portion of the label can be read and scanned

greaters graph and an abe for sapp group. The Four and Lander of Alphan States of the Company Aore to the sideou

Use of this system constitutes your agreement to the service conditions in the current FedEx Service Guide, available on fedex corn FedEx will not be responsible for any claim in excess of \$100 per package, whether the result of loss damage, delay, non-delivery,misdelivery,or misinformation, unless you declare a higher value, pay an additional charge, document your actual loss and file a timely claim Limitations found in the current FedEx Service Guide apply Your right to recover from FedEx for any loss, including intrinsic value of the package, loss of sales, income interest, profit, attorney's fees, costs, and other forms of damage whether direct, incidental,consequential, or special is familiated to the greater of \$100 or the authorized declared value. Recovery cannot exceed actual documented loss Maximum for items of extraordinary value is \$500, e.g. jewelry, precious metals, negotiable instruments and other items listed in our ServiceGuide. Written claims must be filed within strict time limits, see current FedEx Service Guide.